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Ellis L. Reinherz

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EXAMINER

LONG, SCOTT

ART UNIT

PAPER NUMBER

1633

MAIL DATE

DELIVERY MODE

03/26/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

## Application No.

10/783,994

## Applicant(s)

REINHERZ ET AL.

## Examiner

Scott D. Long

## Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 9-39 is/are pending in the application.
- 4a) Of the above claim(s) 9 and 13-38 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-3 and 39 is/are allowed.
- 6) ☒ Claim(s) 4-6 and 10-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/888)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

*The examiner acknowledges receipt of Applicant's Remarks and Claim amendments, filed on 8 January 2008.*

#### ***Claim Status***

Claims 1 and 10 are amended. Claims 7-8 are cancelled. Claims 9 and 13-38 are withdrawn from further consideration by the Examiner, pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions, there being no allowable generic or linking claim. Claims 1-6, 10-12, and 39 are under current examination.

#### ***Priority***

This application claims benefit from PCT/US02/08288 (filed 14 March 2002) which claims benefit from provisional US Application 60/314,046 (filed 22 Aug 2001) and from provisional US Application 60/322,993 (filed 18 Sept 2001). The instant application has been granted the benefit date, 22 August 2001, from the application 60/314,046.

#### ***Response to Arguments - Claim Rejections 35 USC § 112***

Applicant's arguments filed 8 January 2008 have been fully considered and they are persuasive.

The applicant has canceled claim 7. Therefore, the rejection of claim 7 is moot.

Accordingly, the rejection of claim 7 under 35 USC 112, first paragraph is hereby withdrawn.

***Response to Arguments - Claim Rejections 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1-2 as anticipated over Lamerdin et al. (Genbank Accession No. AD000864, 3/22/21997), is withdrawn in response to Applicant's amendment or arguments. However, Claims 4-5 remain rejected as anticipated over Lamerdin et al. (Genbank Accession No. AD000864, 3/22/21997) for the reasons of record and the comments below.

Applicant's arguments filed 8 January 2008 have been fully considered but they are not persuasive in regard to claims 4-5.

The applicant's amendments cancelling portions of claim 1 (particularly options iii and iv) have overcome the rejection of claims 1-2 as anticipated by Lamerdin et al.

The applicant has argued that claims 4-5 are not anticipated by Lamerdin et al. In particular, the applicant states, "Lamerdin *et al.*, discloses a 39,146 base, single-stranded DNA sequence. This sequence does not consist of or comprise an isolated nucleic acid sequence that encodes SEQ ID NO: 2 because the Lamerdin *et al.* sequence ***needs to be manipulated*** into the reverse sequence ***and*** converted to a complementary sequence ***and*** correctly translated in-frame before it comprises a

nucleic acid sequence that encodes SEQ ID NO: 2. There is no teaching in Lamerdin *et al.* of performing any and all of these steps." (Remarks, filed 1/8/2008, page 12).

While the examiner fully agrees with the applicant that Lamerdin *et al.* does not teach manipulation of their sequence into the reverse complement and further translation, the examiner disagrees with the applicant regarding whether the sequence of Lamerdin *et al.* inherently teaches the limitations of claims 4-5. If we break down the limitations of claim 4, we find there is really just a single structural limitation to the claim, namely "an isolated nucleic acid molecule comprising a nucleic acid sequence that encodes SEQ ID NO:2." It is well established that DNA is a double-stranded molecule and that the sequence of a single strand inherently defines the sequence of its complementary strand. Lamerdin *et al.* teach a genomic DNA sequence which comprises the complement of all of the 15000 bases of SEQ ID NO:1. For this reason, the examiner has interpreted the Lamerdin sequence as being a nucleic acid molecule comprising a nucleic acid sequence that encodes SEQ ID NO:2. A few different molecules could encode SEQ ID NO:2. For example, a cDNA molecule can encode SEQ ID NO:2. The instant Specification (page 2, lines 20-27) indicates that SEQ ID NO:1 can encode SEQ ID NO:2. The examiner believes that the Lamerdin sequence (GenBank sequence AD000864 which comprises the complement of SEQ ID NO:1) inherently teaches SEQ ID NO:1 and therefore inherently teaches a nucleic acid sequence which encodes SEQ ID NO:2. The examiner fully acknowledges that, in all likelihood, Lamerdin *et al.* did not recognize that their sequence encoded a polypeptide that reduces NF- $\kappa$ B-sensitive reporter activity in Cos cells. However, since this attribute

of SEQ ID NO:2 is inherent to the polypeptide, the examiner believes that this limitation is inherent to the sequence of Lamerdin. Therefore, the examiner reasserts that the sequence taught by Lamerdin et al. teaches the limitations of claims 4-5 directed to an isolated nucleic acid molecule comprising a nucleic acid sequence that encodes SEQ ID NO:2, and consequently also teaches the NF- $\kappa$ B-sensitive reporter activity.

Accordingly, the examiner hereby maintains the rejection of claims 4-5 as anticipated by Lamerdin et al. However, the rejection of claims 1-2 as anticipated by Lamerdin et al. is hereby withdrawn.

***Response to Arguments - Claim Rejections 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection of claims 1-3 under 35 U.S.C. 103(a) as obvious over Lamerdin et al. (Genbank Accession No. AD000864, 3/22/21997), is withdrawn in response to Applicant's amendment or arguments. However, Claims 4-6 remain rejected as obvious over Lamerdin et al. (Genbank Accession No. AD000864, 3/22/21997) for the reasons of record and the comments below.

Applicant's arguments filed 8 January 2008 have been fully considered but they are not persuasive in regard to claims 4-6.

The applicant's amendments cancelling portions of claim 1 (particularly options iii and iv) have overcome the rejection of claims 1-3 as obvious over Lamerdin et al.

The applicant has offered two specific arguments regarding the rejection of claims 4-6: (1) the examiner has failed to state a prime facie case of obviousness by not providing some teaching, suggestion, or motivation in the prior art that would have lead one of ordinary skill to modify the prior art to arrive at the claimed invention and (2) there is no teaching or suggestion of a polypeptide that reduces NF-kB-sensitive reporter activity in Cos cells by Lamerdin et al., nor is a polypeptide with this activity intrinsic to Lamerdin et al. sequence because the Lamerdin et al. sequence needs to be manipulated before it comprises a nucleic acid sequence that encodes a polypeptide that reduces NF-kB-sensitive reporter activity in Cos cells.

Regarding the applicant's assertion that the examiner failed to state a prime facie case, the examiner disagrees. The examiner suggests that in light of the recent KSR decision, this necessity for a "reason or suggestion" is no longer required. KSR forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding of obviousness. See the recent Board decision *Ex parte Smith*, -- USPQ2d, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007) (citing KSR, 82 USPQ2d at 1396). The examiner has provided logical reasoning why a skilled artisan would understand the sequence of Lamerdin et al. to be obvious over instant claims 4-6. In the following paragraphs the examiner discusses how the teachings (GenBank

sequence AD000864) of Lamerdin et al. would lead one of ordinary skill to modify the prior art to arrive at the claimed invention.

The applicant's second argument (Remarks, page 14) suggests that claims 4-6 are not as obvious over Lamerdin et al. In particular, the applicant indicates, the Lamerdin et al. does not teach or suggest a polypeptide that reduces NF-kB-sensitive reporter activity, nor is such a polypeptide intrinsic to Lamerdin. The examiner points out that the rejected claims are not directed to a polypeptide, but to nucleic acids. Therefore the examiner finds this argument unpersuasive because the applicant seems to be arguing limitations which are not in the claims. The applicant further suggests the Lamerdin *et al.* sequence does not consist of or comprise an isolated nucleic acid sequence that encodes SEQ ID NO: 2 because the Lamerdin *et al.* sequence ***needs to be manipulated*** into the reverse sequence ***and*** converted to a complementary sequence ***and*** correctly translated in-frame before it comprises a nucleic acid sequence that encodes SEQ ID NO: 2. There is no teaching in Lamerdin *et al.* of performing any and all of these steps."

While the examiner fully agrees with the applicant that Lamerdin et al. does not teach manipulation of their sequence into the reverse complement and further translation, the examiner disagrees with the applicant regarding whether the sequence of Lamerdin et al. intrinsically teaches the limitations of claims 4-5. If we break down the limitations of claim 4, we find there is really just a single structural limitation to the claim, namely "an isolated nucleic acid molecule comprising a nucleic acid sequence that encodes SEQ ID NO:2." It is well established that DNA is a double-stranded



molecule and that the sequence of a single strand intrinsically defines the sequence of its complementary strand. Lamerdin et al. teach a genomic DNA sequence which comprises the complement of all of the 15000 bases of SEQ ID NO:1. For this reason, the examiner has interpreted the Lamerdin sequence as being a nucleic acid molecule comprising a nucleic acid sequence that encodes SEQ ID NO:2. A few different molecules could encode SEQ ID NO:2. For example, a cDNA molecule can encode SEQ ID NO:2. The instant Specification (page 2, lines 20-27) indicates that SEQ ID NO:1 can encode SEQ ID NO:2. The examiner believes that the Lamerdin sequence (GenBank sequence AD000864 which comprises the complement of SEQ ID NO:1) intrinsically teaches SEQ ID NO:1 and therefore intrinsically teaches a nucleic acid sequence which encodes SEQ ID NO:2. The examiner fully acknowledges that, in all likelihood, Lamerdin et al. did not recognize that their sequence encoded a polypeptide that reduces NF-kB-sensitive reporter activity in Cos cells. However, since this attribute of SEQ ID NO:2 is intrinsic to the polypeptide, the examiner believes that this limitation is intrinsic to the sequence of Lamerdin. Therefore, the examiner reasserts that the sequence taught by Lamerdin et al. teaches the limitations of claims 4-5 directed to an isolated nucleic acid molecule comprising a nucleic acid sequence that encodes SEQ ID NO:2, and consequently also teaches the NF-kB-sensitive reporter activity.

Claim 6 is directed to the isolated nucleic acid molecule according to claim 4 which is RNA. A skilled artisan would know how to produce an RNA molecule which corresponds to a particular DNA. Therefore, the examiner believes the RNA of claim 6 is obvious over the sequence of Lamerdin et al.

Accordingly, the examiner hereby maintains the rejection of claims 4-6 as obvious over Lamerdin et al. However, the rejection of claims 1-3 as obvious over Lamerdin et al. is hereby withdrawn.

The rejection of claims 10-12 under 35 U.S.C. 103(a) as obvious over Lamerdin et al. (Genbank Accession No. AD000864, 3/22/21997), remain rejected as obvious over Lamerdin et al. (Genbank Accession No. AD000864, 3/22/21997) in view of Liu et al. (Current Biology, 19 November 1998; 8:1300-1309) for the reasons of record and the comments below.

Applicant's arguments filed 8 January 2008 have been fully considered but they are not persuasive.

The examiner finds no problem with two of the three portions of claim 10, namely 10i and 10ii. However, the examiner maintains that 10iii is obvious over Lamerdin in view of Liu.

The applicant's arguments regarding "manipulation" of the Lamerdin sequence have been addressed above, in both the 102 and previous 103 response to applicant arguments. Therefore, the examiner will not unnecessarily extend the length of this action by reiterating these arguments. The applicant also suggests that Liu et al. fails to remedy the deficiencies of Lamerdin et al. As stated in previous actions, the Liu reference was introduced to describe vectors and cells comprising heterologous nucleic acids, rather than to provide a teaching for the claimed sequences. As described in a

previous action (filed 9/19/2006), Liu et al. teach vectors which can accommodate large genomic fragments which would be required for either the instantly claimed sequences or for the Lamerdin sequence.

Accordingly, the examiner hereby maintains the rejection of claims 10-12 as obvious over Lamerdin et al. in view of Liu et al.

***Response to Arguments***

***Claim Rejections 35 USC § 112 (written description/new matter)***

The rejection of claims 1-3, 7, and 10-12 is withdrawn in response to Applicant's amendment or arguments.

Applicant's arguments (Remarks, page 15) and claim amendments filed 8 January 2008 have been fully considered and they are persuasive.

The applicant has canceled claim 7. Therefore, the rejection of claim 7 is moot. Additionally, claims 1-3 and 10-12 have been amended to remove language which the examiner asserted was new matter.

Accordingly, the rejection of claims 1-3, 7 and 10-12 under 35 USC 112, first paragraph (new matter) is hereby withdrawn.

***Response to Arguments - Claim Rejections 35 USC § 102***

The rejection of claim 39 as anticipated over Lamerdin et al. (Genbank Accession No. AD000864, 3/22/21997), is withdrawn in response to Applicant's amendment or arguments.

Applicant's arguments filed 8 January 2008 have been fully considered and they are persuasive in regard to claim 39.

The applicant argues that Lamerdin et al. (Genbank Accession No. AD000864, 3/22/21997) does not teach an isolated nucleic acid consisting of a nucleic acid sequence that encodes SEQ ID NO:2. Support for this claim language is found in the specification on page 2, lines 19-22. Upon further consideration of the teachings of the specification, the examiner finds his previous rejection unsupportable under this statute. The examiner believes the specification does not recite both broad and narrow claim language that would allow the examiner to reject claim 39 under 35 USC 102(b) as anticipated by Lamerdin et al.

Therefore, the examiner hereby withdraws the rejection of claim 36 as anticipated by Lamerdin et al.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Claims 1-3 and 39 are allowed. Claims 4-6 and 10-12 remain rejected.

***Examiner Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**. The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Weitach** can be reached on **571-272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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